



# Division of Diabetes Treatment and Prevention

## Early Life Intervention for Diabetes Prevention

**Ann Bullock, MD, Allison Barlow, MA, MPH, PhD, and Jennifer Richards, MPH**

Jan Frederick:

Dr. Bullock, please start out by telling us about yourself and giving us an overview of what we're going to hear about today.

Dr. Ann Bullock:

Well, thank you, Jan, and welcome everyone. We're so pleased as Jan said that you all could join us today for this conversation around what type of risk factors in early life influence obesity and are there some things we can maybe do to reduce some of those risk factors? So, it's great to have Dr. Barlow and Ms. Richards with us. We're so appreciative of their time and look forward to their words.

So today, what I'll be talking about, first of all, is we'll give an overview very quickly because there's so much science here. So all it can be is a quick summary of the risk factors for obesity that we know are already there in the in utero or pregnancy period and in the first few years of life, and I'll talk a little bit about some of the evidence there is for interventions during these critical periods. Then at that point, I will turn things over to Allison and Jenny and they will talk about the Family Spirit Intervention. They'll give a description of it and then also talk about some of the results that have just been published that show effectiveness and the exciting thing -- well, there's a lot of exciting things about it, but perhaps the most important one is that this is happening in our patients, our community members, our colleagues, our brothers and sisters in communities just like ours and that is an exciting thing.

So as Jan said, I'm Ann Bullock. I'm a family physician and I've been in Indian Health Service for 25 years. I am the Acting Director for IHS Division of Diabetes and an enrolled member of the Minnesota Chippewa Tribe. For those of you who know me know that this has been an interest of mine for an awfully long time and I'm so excited that we've got this opportunity to tell you about the Family Spirit Intervention.

So as we get going thinking about the early life risk factors, just a quotation to start off with from a recent article in the nutrition journal that "the exquisite system for regulation of energy balance is established just once in each individual's life. In addition to the instructions laid down on the genetic blueprint, environmental influences during critical ontogenic or developmental periods determine the outcome of this process, with permanent consequences for body weight regulation." Those critical developmental periods focus so much around the in utero and early life that this seems to be a place where we would indeed want to intervene.

So for those of you who have heard me talk on this before, you'll see a few familiar slides and some concepts we've talked about in the past, but I'm assuming many of you are not as familiar with this topic. So for those of you which this is a review, I hope that it's useful; and for those of you for whom this is newer information, I hope this will at least give you a little taste of the amazing amount of information available in the literature today, talking about what happens to us early in life has impact on our health and well-being, including our obesity risk for the rest of our lives.



So this is a slide that I've used for quite some time because it's a nice model to demonstrate that the several parts of what happens in the womb have huge impacts and sort of on this left column here, you'll see substrate restriction which really relates to placental problems and decrease in oxygen or some problems that way. But for the purposes here, which more commonly is that there simply isn't enough nutrition, good nutritional building blocks, whether it would be amino acids or the micronutrients in order to build all the cells and organs that we need for a healthy body. So when there's not enough nutrition or nutritional building blocks, what can happen is that there's actually a decrease in the number of cells in organs and if there's quite a deficiency in nutrition available, it could even affect overall organ growth or even the growth of the baby itself, including the fetal growth. This has been shown for a number of organs to be the case, particularly the kidneys and the pancreas, which of course have huge implications for high blood pressure and for later diabetes risk. So, inadequate nutrition in pregnancy has huge implications for later chronic disease.

On the right side column, you'll see there's adaptations to stress; so an increase in the stress hormones, which include cortisol and other glucocorticoids, but also a decrease in the hormones that help us to grow and build healthy bodies and organ systems. So when you put together smaller organs with fewer cells together with this change in the set points for many of the hormones, which regulate the body, that in the middle you'll see all those arrows, they go up and down. You'll see that our ability to produce insulin can be less if there's fewer cells in the pancreas to do so, all those stress hormones telling the liver to put out glucose, then glucose levels rise. If there's not enough nutrition to build brains and organs, then there's definitely not going to create healthy skeletal muscle and that's a problem in many ways and one of which is that about 60% of glucose in our bodies is burned by our skeletal muscles. So if there's less of that, then we're not going to be able to burn as much energy.

Then going across you have changes and how the heart and the kidneys function. On the far right, you can see that there's an increase in this HPA or stress hormone activity and alterations in growth hormone and insulin growth factors, our appetite regulation right off the bat. Now, all of these things here in those up and down arrows, those are the things that a child is born with if they've been exposed to inadequate nutrition and/or significant maternal stress during that pregnancy. So you've already got this whole constellation of risk factors already put together and you're just born. So just below that, now the child is born, they come out to the world with altered insulin regulation and increased appetite because essentially they've been starved in the in utero period and they come out hungry. Once they figure out how to latch on to the bottle or nipple, they start eating and they just keep going and they would have this catch up growth, and then all of this cascading of visceral obesity changes and in the way the heart and the kidneys are regulated and pretty soon obesity comes along and it's the kind that is the more metabolically active. It's the kind of obesity that is visceral where the fat is laid down within the viscera or the abdomen.

Put all that together over the years, especially if nutrition continues to not be good. If all that's available is inadequate amounts of nutritious foods and too much of junk foods because of food insecurity and because of ongoing stressors in their life altogether, you can see that the outcome not surprisingly understanding this is diabetes, obesity and heart disease. So what happens in the womb is hugely important for set points and regulation and prediction of all these kinds of problems right from the get-go.

So, we know maternal stress, nutrition, and pregnancy do increase offspring obesity risk and there's an article there from Journal of Nutrition and Metabolism on that. And here's just a few more studies that back up the model we were just discussing. We have the fetuses of obese mothers develop insulin resistance in the womb, even before they're born. The maternal diet affects pregnancy and epigenetically, epigenetics is the way we turn genes on and off. So that if mom does not have a good diet in pregnancy, that's been shown to alter gene expression in the child and increase their risk for being heavy at age nine and there's this study in Diabetes that says

"our findings suggest a substantial component of metabolic disease risk has a prenatal developmental basis."

Maternal stressful life events during the first trimester, before many women even know they're pregnant increase the risk of pre-term birth and having the child born small for gestational age. The odds ratio is two-and-a-half times greater if mom has a significantly stressful life event in the first trimester. That's a very impressive thing especially when you consider that there's an inverse association between gestational age and insulin levels. Meaning, the earlier you are born, the higher your insulin levels are, already more insulin resistance. This has been shown both at birth as well as checked in about the first or second year in childhood. So that increased insulin level continues and that was just from an article in JAMA just a few months ago.

So both being born small for gestational age and being born pre-term, both of those are strongly associated with later risk for chronic diseases, including heart disease and diabetes. So again, over and over again, evidence in the literature shows that what happens to us in the womb has huge implications for later in life. Many of you are familiar with this, but if you're not I want to make sure you know about the Adverse Childhood Experiences (ACE) study.

So if a child is born with all those risk factors because of maternal stress and inadequate nutrition, now they come out into a world where things don't go always right there either. The Adverse Childhood Experiences study was a study in over 17,000 HMO enrollees in California and they asked those folks whether they had experienced any of eight to ten, depending on which study they were in, but for our purposes now we'll talk about the eight categories of adverse experience and those are listed there, physical, emotional or sexual abuse, growing up with a mentally ill, substance abusing or incarcerated family member, ever seeing your mom beaten and parental separation or divorce. In this primarily Caucasian, amazingly high rate of college education population – which should have been a lower risk group, two thirds of them said yes to at least one.

Well, Mary Koss and her colleagues did a similar study among seven tribes in the Southwest, and so when you look at these numbers here, you see that the overall exposure reported by the folks from the tribal groups was 86% said yes to at least one. So as you look at that list, non-Native is the California Kaiser study and then Native was the one done with the tribes in the Southwest. You see really high rates on all of those things. For the Native studies, you can see that two thirds of the people who participated, and this was over 1,600 of our folks from the Southwest who did participate in that study and they said yes to household alcohol, growing up with some who abused alcohol in their family as they grew up.

The last category is four or more adverse childhood experience categories, four or more of those things that are at the top of that slide. So what happens if you had four or more of them? Well, you're far more likely to be dealing with alcoholism as an adult to begin with drug abuse, depression and to have made a suicide attempt, huge, huge correlations, much more likely to smoke, to have gotten pregnant as a teenager, to have gotten a sexually transmitted infection.

So many of these things that have huge implications for health and mental health across the lifespan and obesity was one-and-a-half times more likely in folks who had an ACE score of at least four. In fact, at all levels of ACE, where they call a graded relationship, there were increased risk for everything, including heart disease itself. A graded relationship business means that having one ACE was worse than zero. Four was worse than three; seven was worse than six and so on, meaning that it's a dose-dependent relationship. The more of this you experience, the higher your risk for all those things.

Now, many studies since this ACE study happened have looked at things, that same issue in other countries around the world in many different groups and have found amazingly similar things. In this study, in ten countries, adults who experienced at least three childhood adversities were

almost two thirds more likely to have diabetes, more than twice as likely to have heart disease and in fact the risk between similar associations you see between cholesterol and heart disease and the risk between adverse childhood experiences and heart disease. So while it's important for us to put people on statins and get them to quit smoking and things to help to reduce their heart disease risk, we often overlook this huge issue that contributes to this heart disease risk too, which is what has happened to them in their childhood.

ACEs affect children at the time, not just waiting until adulthood. There's this strong graded relationship again, as you can see, sort of stair-stepping right up as the number of adverse risk factors just increase. In fact, by the time we get up to six or seven risk factors, it's virtually 90 to a 100% chance that a child will be experiencing developmental delay – so, profound.

We know that stress in children is positive; it can be positive, it's necessary. Not all stresses are bad. There's lot of things that help us learn mastery and as long as we have good support, no problem. Then there are things that we might call tolerable stressors. These are more severe and may last longer. It can be huge, like the loss of a parent even, but if it's buffered by some relationship with a supportive adult, the brain and body can often recover from these with not necessarily a whole lot of long term consequences. But of course, the type of stress that is most difficult for children is often called toxic stress, which is strong, frequent, prolonged adversity, abuse, neglect, if the caregiver is dealing with mental illness, even poverty itself is a toxic stressor. If there is no adult support or inadequate support, this indeed can disrupt both brain and organ function in the long term, and this slide has a list of all the many areas of development that are affected when children are dealing with complex trauma or toxic stress during these critical developmental periods.

So, stress in children and obesity risk, just a few studies as examples, in this one being exposed to intimate partner violence almost the doubled the risk of obesity in children by the age of five. This was not being beaten; it's watching it happen to mom or whoever. If children just don't have a good relationship with their primary caregiver or usually with the mother, huge increases in risk of obesity. In this study, the researchers literally followed around moms and kids in their first few years of life and as objectively as possible rated the quality of that relationship, and those that had poor quality relationships compared with those who had good quality were two and a half times more likely to develop obesity as adolescents ten years later compared to those with good relationships. In this study, children who experience multiple negative life events basically ACE kind of things were indeed at higher risk of being overweight by age 15. So these things happen early and young.

So I hope that this quick look through the risk factors is something that maybe is now more familiar for you. There's a lot more studies out there, but we want to move on now to where there's some new hope for intervention. Can we do something about this? Knowing the risk factors doesn't mean that we necessarily have interventions that can successfully reduce risk factors and more importantly reduce the outcome that we're trying to avoid. But we know that this paper from Harvard University says we know that sound maternal and fetal nutrition, combined with positive social and emotional support of children through their family and community environments will reduce the likelihood of negative epigenetic modifications that increase the risk of later physical and mental health impairments. So yes, they are saying yes, there are things we can do to make a difference in this.

One of those things, and this is from our community study in the American Medical Association Journal this last year, looked at over a 100 of our tribal communities and tribal communities that opened or expanded existing casinos during the study period. This was associated with not only increased economic resources as of course you'd expect, but also the decrease in child obesity and overweight. So just reducing the stress of poverty helped to improve weight in children. That's pretty profound. So Neal Halfon from UCLA wrote the accompanying editorial that went along with that paper and he noted that "growing up in a family that is struggling economically in a

neighborhood that is plagued with failed schools, crime, disorder and violence creates cumulative health risks and functional deficits that contribute to higher rates of many health conditions, including asthma, attention-deficit/hyperactivity disorder and obesity. Without a coherent and functional system of high quality services such as child care, early education, family support, healthcare and mental health services, risks go unaddressed, preventable health problems develop, and disabling conditions compound over time, becoming more pronounced as sick and impaired teens become chronically ill and disabled adults.” So Dr. Halfon nicely summarizes both the problem and also where some of the solutions are. We’ve got to have a way to intervene in these issues that happen with poverty and with other stressors.

So we’re going to focus of course today on home visiting. There are something like a dozen or more evidence-based home visiting interventions now and they are all good. They all have evidence. They’re all recommended by Health and Human Services as being evidence-based and we certainly don’t mean to say that there are only one or two that are good. There are many. But home visiting has been studied now for a long time. The longest running model is the nurse-family partnership home visiting model and now has evidence going out to age 19 and beyond that there are still positive effects from an intervention that happened not only during mom’s pregnancy, but stopped by the time the child was age two. How many things have positive effects almost two decades after you stop doing them? That’s incredible.

Many of you are familiar with what’s often called MIECHV Funding, which is part of the Affordable Care Act. There are 25 tribes and tribal organizations funded through this to provide home visiting. We would love to see even more, be able to do it.

These next few slides are from Nurse-Family Partnership Research. So from a different home visiting model. We’re not going to spend too much time looking at this, but just quickly seeing that if we intervene and do the right thing early, we could benefit in many domains. Here is academic achievement and language development. This one is whether children are hospitalized for injuries, mom being able to determine how closely spaced she wants to have her children. It’s a huge indicator of child well-being, how close children are spaced together and how many of them there are.

This is also looking at economic well-being of the family, how long did they need welfare assistance? How long did they receive food stamps? With these kinds of interventions, these are meaningful differences in the lives of families and communities. Nurse-Family Partnership has been shown to reduce cost in lower risk families, but in high risk families it’s a seven to one ratio of dollars saved compared to dollars spent. So this is a slide from the Center on the Developing Child at Harvard, which again is looking at Nurse-Family Partnership as the middle one showing a return on investment. Perry Preschool was in Chicago in the 1970s and another one we’re going to talk about is the first one, the red bar, which is the Abecedarian Project, showing again return on investment. This now was a paper that was just in Science last year entitled ‘Early Life Investments Substantially Boost Adult Health’.

So the Carolina Abecedarian Project was done in low income areas in Raleigh, North Carolina. Four cohorts of disadvantaged children born in the mid ’70s were provided interventions, which I’ll describe briefly in a minute here, from the time they were born until age five. So that intervention consisted of services that focused on development of language, focused on emotional regulation, and focused on cognitive skills. They were given supervised play and provided very effective intensive daycare type of settings. They were provided good nutrition, so they dealt with the nutrition problem as well. They had two meals and a snack at the childcare center. So even if there wasn’t enough food at home or enough good food, they had enough through this intervention and they also received primary pediatric care. So, medical care as well and developmental screening.

Now, flash forward, these folks are now, at the time of this paper, they were in their 30's and they have lower prevalence of CVD and metabolic disease risk factors including better blood pressures, A1Cs, lower BMI's and HDL cholesterol, all from an intervention that happened long ago but happened at the critical time when there was opportunity to make a difference.

So as this American Academy of Pediatrics position paper says, science is showing us that reducing toxic stress can target a common physiologic pathway implicated in an enormous array of health outcomes from asthma to cardiovascular disease. Doing the right things young can have good impacts. Unfortunately, for too many children, the wrong things are happening and they happen too frequently.

So going forward, what works? That's the question we all want to know. We all want to do the right thing. We need to have evidence of what those right things are. So we know that exposures in the pregnancy or in utero periods in early life, have significant impact on later obesity risk. That is clear. The risk factors and associations between risks are being defined. There's still, a ways to go on that but we are understanding many risk factors. We know that if children don't get sufficient sleep, their bodies don't learn good circadian rhythm regulation around food and sleep and other things that increases risk for obesity as well as risk for things like ADHD and other problems. So many of these things are being defined, while there's much yet to learn.

We're even starting to understand how some of this works, some of these epigenetic things, developmental programming, so many other mechanisms. Again, long way to go but many of these are starting to be understood.

In terms of interventions, this research is also still in its infancy, but a part of the picture is starting to emerge. What we are seeing is pretty clear how important it is for children to have good, caring, loving adults in their lives, how important adequate amounts of both quantity and quality of nutrition in the in utero and in early life periods. But even before mom and dad conceive that child, their nutritional quality also affects what happens for that child going forward.

So nutrition, reducing stress and reducing adverse childhood experiences, and if they happen, intervening in them early, these are all things that we are seeing evidence, they make a difference down the road. So early intensive interventions can reduce some of the risk factors for whether its obesity or heart disease or mental health problems, drug abuse, all kinds of things.

Do they reduce obesity itself? That has yet to be shown. We know they reduce risk factors as Allison and Jenny are about to tell you but in terms of obesity itself, that's a randomized control trial yet to happen. But we know, they're reducing risk factors, and that is a darn good start especially when it's happening in our population as you're about to hear.

So for Family Spirit, before I turn it over to Allison and Jenny, I just wanted to convey not only my appreciation for them joining us today, but my sincere admiration. While many people have looked for other types of interventions that are a little bit more about or ignoring the psychosocial and economic issues that people deal with that hugely affect their lives, Allison and her colleagues, both at Johns Hopkins and at the tribal sites in the Southwest have put their money where their mouth is and they have said, "Let's try something," and they work together to develop the curriculum and to study it. Luckily, what they've found are the good things that our tribal communities have always known. We take good care of our young people. We take good care of our pregnant women. We take good care of our parents, who are parenting the young children. This is the type of wisdom that science is coming back around again, and which Family Spirit is capitalizing on.

With that, I want to turn things over to Allison and Jenny and check back with you all at the end of the presentation. Thank you!

Allison Barlow:

Thank you so much. This is Allison Barlow. I just want to thank Dr. Bullock so much and Jan Frederick. Dr. Bullock has an incredible ability to take a large amount of complex information and help us wrap our minds and hearts and I think spirits around it. So I really express my deep gratitude to her for that incredible capacity.

I'm at Johns Hopkins Center for American Indian Health where I've worked for the past 23 years and it is such a pleasure to talk to all of you today. I'll pause for a second and let my colleague, Jenny, introduce herself.

Jenny Richards:

Hi, this is Jenny Richards. I'm a Senior Trainer and Affiliate Liaison with the Family Spirit Program. I am Diné, Oglala Lakota, and Taos Pueblo and I'm based in Tuba City, Arizona on the Navajo Nation. I'm very glad to be here, so thank you for listening to our presentation and I look forward to fielding any questions later.

Allison Barlow:

Thank you, Jenny. So, just a brief background on our Center, so Johns Hopkins Center is established at the Johns Hopkins School of Public Health here in Baltimore, but we've had more than three decades of work and partnership with American Indian communities that originated in the Southwest, and I'll show you a map, but now have quite a national scope. We have an MOU with Indian Health Service that dates back to 1991 and that was first initiated by Dr. Everett Rhoades and every successive IHS Director has renewed that Memorandum of Understanding. Its purpose is really for our center to work in partnership with IHS to leverage our resources to achieve the best possible health and education for American Indian communities.

As I've mentioned, we've had a three-decade partnership with Southwestern Tribal communities. In these communities, we have nearly a hundred Native staff who work there on the programs that we've co-created with the communities. Now, these same programs have been scaled all over the United States, some abroad. We also have a large training program and some of you may have participated but we conduct winter and summer institutes at Johns Hopkins and American Indian Health and Public Health. So I'd love if you wanted to contact me about the scholarships we have available for those programs as well as our masters and PhD level training. Please contact me directly and I can get you more information.

So our Center really has three concentric circles of work that we do. Our original work really focused on infectious disease research in the 1980s and 1990s and to many of you that will be obvious that the largest disparities at that time, the 1980s, among American Indian children compared to the general US population really was focused in infectious disease. But as I'll show you later and as you know, the landscape is really changing.

The Behavioral Health Programs began at our center in 1991 and have really grown. The training and scholarship programs began in 2000 and we have an endowment at our center that supports those programs and allows us to provide many scholarships for our Native American scholars at Johns Hopkins. So the Behavioral Health Programs span many different issues but the one we'll be talking about today is our Family Spirit Program that focuses on promoting parenting and strong families in Native communities.

So a little bit about this changing landscape. We know that since the 1980s, there has been a major shift from high infectious disease mortality to now some profound behavioral and mental health inequalities in Native communities. Braided with that is low education employment, modern

trauma heaped on top of historical trauma and families that are really struggling to attain health and prosperity within their homes and their communities.

So when we thought about sort of this cascade of problems, we scratch our heads with our tribal partners and said, "Where should we begin to break this cycle?" We decided that this was the place to start because many of the young parents who are suffering the stressors that Ann mentioned are embedded in multigenerational families. If we can work together with local employees who are serving those families, we have a chance to break this cycle.

So Jenny's now going to talk specifically about the Family Spirit Program and I'll come back a little bit later.

Jenny Richards:

Thank you, Allison. So as Allison mentioned, how can we break the cycle and what should we look at moving forward? So what we've been working on and implementing is the Family Spirit Home Visiting Program. We're the largest and only evidence-based and culturally tailored home visiting intervention program designed specifically for Native American families. As Dr. Bullock mentioned, there are several models and what really differentiates us is not only the tailoring to American Indian communities but also the utilization of Native American para-professionals; our CHRs, health educators or family health coaches as the core strategy to support young Native parents from pregnancy to three years postpartum.

So, parents gain knowledge and skills to achieve optimum development for their children across the domains of physical, cognitive, social emotional, language learning and self-health. So it's pretty comprehensive. It's prenatal through the child's third birthday. There are a total of 63 lessons taught across six modules. So it's very comprehensive and in-depth.

In terms of our history and background, I'll just go over this very briefly, but as Allison mentioned we've been in the field for a long time. The Johns Hopkins Center for American Indian Health was established in 1991 with the focus on addressing infectious diseases. But in doing this kind of field work, our staff noticed that there was really a need for an intervention in the tribes most youngest and invulnerable families. So as a result, they developed the "Share Our Strength" or SOS project in 1995. This curriculum was developed to address maternal and child health topics and it also served mothers and babies up to six months postpartum.

So that's really where it started, pretty small. Then people, the tribal representatives noticed that there was really nothing for the fathers. So in 1998 the Fathers' Project began and it included curriculum with information on life skills such as employment and budgeting. So from there, the moms said, "Well, we want this information too. We need all of these life skills training too." So for lack of a better term, the two were just essentially merged and they became Family Strengthening. So the Family Strengthening Curriculum was written from prenatal through the child's six-month birthday. This was around the time that the first randomized controlled trials began. So the coloring on here is the blue are the service projects and the yellow are the randomized controlled trials.

So the Family Strengthening Curriculum expanded to cover prenatal through the child's 12-month birthday. The staff renamed it at a local level to Family Spirit. So the name's changed across the years from Family Strengthening to Family Spirit, Cradling Our Future, and then back. Essentially, it expanded to where we're at now. Since 2006, using the evidence based from the Family Spirit evaluation, our program has been replicated in many communities across the United States, which we'll provide an overview on a little bit later. So we're rapidly expanding. We're all over, primarily in the western United States and we have a lot of trainings scheduled in the next few months.



In terms of the intervention itself, at the very core of Family Spirit is the Native para-professional. We're really the first program to provide clear evidence of the effectiveness of para-professionals as home visitors. So the para-professionals, we really capitalize on the strength of them. So they know the culture, often times they're from the community. They're very familiar with the local resources. They're very familiar with who to contact in local community partners. They can relate to what our families are going through, oftentimes they've been through it themselves. A lot of our families may already know them and may already feel comfortable with them. Para-professionals also eliminate the cultural and language barriers that may exist for non-Native home visitors. So they're at the very core of our program.

We're also home and family based. We recognize that family is key in American Indian culture and oftentimes our extended families are very involved in bringing up the child. So we definitely encourage involvement of other caregivers where appropriate. Home based also eliminates the barriers to receiving care; the home visitors go to the home, which makes it a lot easier for the families to maintain involvement across the three years.

Lastly, we're strength-based. We're all very aware of the shortcomings in Indian country and in our tribal communities. With Family Spirit, we focus on the strengths in the communities and we want to connect our families to those strengths, to those resources. So oftentimes our para-professionals are the people who help these young families navigate through the community resources.

In terms of the curriculum overview, this is just a snapshot of what our Family Spirit affiliates receive. On the top left is the curriculum box set. It contains all of the lessons. It contains all of the content with the exception of the messenger bag and the notebook. In the back, we have -- or inside, we have three-hole punched lesson pages. In the back and in the middle, we have our flip chart binder, which is what the lesson pages go on to and I'll show that in another picture as well. We have our evaluation CD, which has all of the evaluation tools, both recommended and optional as well as certificates for milestones and other tools that they might need further down the line. We also have manuals, a reference manual which has more in-depth information on all of the Family Spirit content, a participant workbook on the left that has all of our handouts and any interactive activities that the home visitor will do with the families, and then lastly the implementation guide. There's also lesson plans inside the curriculum box as well.

In terms of the lesson presentation, on the left, the participant will see a visual and they'll have this binder, the lesson pages are on the binder and it will be to the side of the health educator. The participant will see the visual, oftentimes we'll use scenarios. Scenarios are used throughout the curriculum to present the lesson in a real world context and it is also used to start a dialogue with the participant. What the health educator or the CHR sees is on the right. So they'll see an overview page and they'll use it to introduce the lesson to the participant. Each lesson has teaching points, which are at the top, and teaching points really deliver the key take home messages for the lesson and then underneath the teaching points are the supporting information. So, it's essentially a script with bolded information for the really important content that we want the family to really takeaway, but we really encourage the health educator to get familiar with the information so that they are not reading it verbatim.

In terms of the key content, it's a lot of information. It's three years worth of information. We really wanted to make it as holistic as possible, so you'll see MCH topics in here, but you'll also see life skills development. So we talked to them about how to get a job. We'll go through role playing with them. We'll also talk to them about problem solving and goal setting and how to apply that to different areas of their life or these mock scenarios. We also do nutrition education, physical fitness, the importance of that, meal planning. So it's very comprehensive as you will see here.

The other thing that really differentiates us as a home visiting model is that we really try to tap into the cultural aspects within our tribal communities, namely, the concept that children are sacred. In many of our tribal communities, the word for children literally translates to the sacred ones or the sacred beings. So we really want to bring back those cultural teachings and get back to where it really is important how we bring up our children. We also want to tap in to the matrilineal societies -- many of our tribal communities are matrilineal, meaning that the mother and the children are really the backbone of our society. So they're the agents of change. So, our hope is that by influencing behavioral change in the mothers and the children, we're influencing behavior change in a broader sense of the families and the communities.

We also talk about cultural teachings around what is a healthy person, what is a healthy woman and a healthy family. So this is changing women here, but it applies to any tribe. So from a cultural standpoint, what is a healthy woman, how is she a healthy mother, and let's talk about that and how do we get there. It says here, "Sunrise ceremony in Kinaalda". So that means, in many of our rites of passage ceremonies have inherently protective factors and really important cultural teachings. So we talk about that. What are some cultural teachings that we can take from our rites of passage ceremonies and apply them in a modern contemporary way, in ways that these families can really utilize them in child rearing and in just the way that they live to be healthier.

So, we're really trying to tap into the cultural aspects and are hoping to have an intergenerational impact. We're hoping that more caregivers will get involved and we're hoping that we're using these protective factors to really break the cycles, the negative cycles that Allison spoke about earlier. I mentioned this a little bit earlier, but we really try to keep our content culturally grounded. So we encourage all of our CHRs, our health educators to use familiar stories to create dialogue between them and the families in whatever way they can. It's funny, but our families, we talk about gatherings at basketball games and Pow Wows and the rodeos. These are all very culturally grounded in a sense that this is where the gatherings are. So we really encourage them to do that.

We also use illustrations that they can really identify with. We have a Navajo Apache artist Dustin Craig who did all of our illustrations for us, and then we have outtakes for cultural teachings. So they're in there, they're very flexible, it's just a way for the health educator or CHR to know that this is where you might want to talk about cultural teachings or you might want to ask them what their family believes in terms of cultural teachings because every family is different. Culture is such a flexible word in the sense that it could be traditional; it could be a contemporary culture within that community.

So we talk about traditional parenting as well, especially with regards to safe sleep. We talk about cradle board teachings. We mention use traditional teachings around fitness. With Navajo where I'm at, we have spiritual beliefs about running in the morning, and so we encourage them to use that. Other tribes, they're very active in Pow Wow and we say, "That's a form of physical fitness," and use that. We talk about traditional food preparation and how traditionally we ate very, very healthy, is there a way we can get back to incorporating some of those healthier foods and healthier food preparation.

So, we try to incorporate culture in as many ways as possible, and I talked a little bit about all of these, but we also use the American Indian Life Skills Development and we have that adapted into our program as well. We try as much as possible to encourage the sites to use these teachings where applicable. So with that, I'll go ahead and turn it back over to Allison. She can talk more about our evaluation outcomes.

Allison Barlow:

Great. Thank you, Jenny. So as Jenny mentioned, when you saw that slide that had the light blue and yellow boxes, the yellow boxes represented time periods where we were doing randomized

controlled trials of the outcomes of the Family Spirit Program and in each case we worked very hard with the communities to create beneficial experiences for the mothers who participated in the control group. But this slide shows you the impacts that have been corroborated by the three trials and we really designed the program to affect three different large domains. Parenting, which I think was the primary focus of the Family Spirit Intervention, but almost just as important is really those maternal stressors that Dr. Bullock talked about that really can get in the way of mom being able to parent effectively. If she's experiencing substance use in her home or from her own substance use, if she's experiencing depression, if she has other risky behaviors that are taking her away from being able to parent her child. All of those things are going to get in the way of her actually implementing positive parenting.

We hypothesized if we were able to actually promote parenting, promote better maternal outcomes that the child outcomes would follow, and that's exactly what we've been able to show across the three trials. So in the parenting domain, an increase in maternal knowledge around child rearing, increase in parent self efficacy, reduced parent stress and improved home safety attitudes. Our moms and the child moved a lot and on average moved more than two times a year, so we were not able to measure specific outcomes in the homes becoming safer because they really weren't in control of their home environments. That's what we found in the program.

So that really underscores the importance of that, of the home visitor being from the community and know where to find the mom when she moves and having that very strong relationship with her and the mother's family. In terms of the mother's outcome, this is the first home visiting trial to show outcomes in early childhood for reducing both mom's depression and her substance use. At baseline, 80% of the moms said they had already used alcohol and marijuana and 40% had used methamphetamines and cocaine. So there were very high rates of substance use and we were thrilled to be able to show decreases in substance use among the moms. I think that really goes back to something like Dr. Bullock shared with us. We really think that stress undergirds the substance use and that's kind of where we're working. So helping moms reduce stress and build skills around parenting is going to help decrease these other problems.

But perhaps most important, in terms of breaking the cycle of poor child outcomes -- the child outcomes that were found in this trial. So we found out that the children who were served by Family Spirit had fewer social, emotional and behavior problems, and I'll go into more depth about that in the next slide. Specifically, we also were able to show that they had lower clinical risk of behavioral problems over their life course, and I'll go into detail in the next slide.

So to measure these outcomes for children, we use this scale called "The Infant Toddler Social and Emotional Assessment." It was designed by Dr. Alice Carter at Massachusetts General Hospital. The problem domains that it measures include these three big terms, externalizing, internalizing and dysregulation. I've tried here just to break these down into more commonly understood English. So externalizing really looks at the subscales of aggression, peer aggression, activity impulsivity and you can read down the list of what these overarching domains are really measuring. In each of these domains, the children who were served by Family Spirit had much more positive outcomes in these three domains.

Part of the scale allows you to look at children who score in the lowest ten percent, in the lower ten percent in a sort of a Bell curve. From national norms, kids who score in the lowest ten percent tend to experience behavior problems across their life course, and we actually were able to demonstrate significantly fewer kids scored in that clinical risk range whose mothers were served by Family Spirit.

Another piece of information that's not shown in the slides, but the mothers who were highest risk coming into the intervention, those with the highest substance abuse and highest depression actually, they and their children experienced the greatest benefit. So what we could see from that

is Family Spirit is effective in serving even the moms at highest risk. It's strong enough to actually make a difference with those moms.

So, back to sort of Dr. Bullock's introduction. So what can we say about the fact that we were able to affect these early parenting and child behavior problems in terms of obesity and diabetes? Generally, what we can say is that these outcomes that were impacted are associated with risk for obesity and diabetes. So taken together, and this is just a list of studies, taken together these outcomes would predict lower risk for obesity.

So, Family Spirit has had, in the last two years, just a great run in terms of gathering some endorsements from national programs. So the Family Spirit has been accepted into SAMHSA's National Registry of Evidence-Based Practices and Programs and it scored the highest score in terms of readiness for dissemination of 4.0 out of 4.0. It also has one of the very highest participant retention rates of all the home visiting models that have been endorsed as evidence-based programs. So at one year postpartum, we've been able to retain 91% of our families, and up to three years 83% which is very high for these home visiting programs. It also received the highest federal rating from the HomeVEE programs.

I'm going to pass the baton back to Jenny and she can talk to you about where we actually have trained tribal communities now to implement Family Spirit and she can finish up our presentation.

Jenny Richards:

Thanks, Allison. So as of now, I believe Family Spirit is in about 40 tribal communities in 11 states. So this map kind of shows the visual of where we are at. This summer, we're going to be expanding pretty rapidly and many of those sites are in Indian Health Service. So we're expanding pretty quickly. In terms of replication, it's a three-phase process. So when we get contacted by an interested site, we'll have a planning phase, we'll host an introductory webinar with them, just kind of going over what Family Spirit is, we'll go over more of the modules. So they can see all of the content that they would be getting. We also do readiness and evaluation tools. So we'll send them tools ahead of time before these pre-training calls and it will basically just ask how will Family Spirit be implemented, who will be implementing it, what do you anticipate their case load to be, what are the types of evaluation tools you use, what do you want to measure.

So we really send these tools ahead of time to get our sites thinking about the implementation so we can pinpoint and troubleshoot any implementation difficulties before the training and we can really talk about it during the training.

We also distribute the curriculum box sets to all of the trainees in advance, at least a month in advance and that was the picture that we showed earlier. We have them do online knowledge assessments. The purpose is for the CHRs, or the health educators to gain familiarity with the curriculum before the training. So, by having done this for several years, we've been able to hone what works and what doesn't work in the training. When we go through the training, we don't go through every single lesson in a lot of detail. We've done this in the past and it's not as effective as focusing on specific topics, working through scenarios and activities and role playing in areas that are really more difficult.

So we have these knowledge assessments. There are five questions per lesson. They're very straightforward, it's open book so they have the curriculum in front of them. It'll show them which questions are incorrect and they can retake it as many times as they want. So it's basically just so they can go through the curriculum and get familiar with the content. It's nothing that we mean to be overwhelming. So we just ask that they pass each assessment at 80% or above. So four out of five questions correct for each lesson.

Then we have pre-training calls. We like to have them at least every other week leading up to the training. The training itself is a weeklong. We'll go there as trainers, we'll focus on how they should deliver the curriculum content, the delivery. We'll go through some of the harder materials, the scenarios and the role play. We'll train them on the evaluation tools that they selected and then at the end we'll give them a certification. Lastly, we have implementation and post training.

So we try to engage with them pretty quickly post training, two weeks, four weeks, six and then we just taper to quarterly check ins. We also have FS Connect opportunities. So we send them newsletters. We have technical assistance webinars, which focus on different things; for example, recruitment and retention. We have quarterly webinars, which focus on different topics that the health educators select themselves. So we had one recently on how to engage fathers in home visiting. We had another one on addressing substance abuse in your home visits, and then most recently we had a great webinar from some Native lactation consultants on how to communicate with families about breastfeeding and why breastfeeding is important and how to provide some basic breastfeeding counseling. So, it's a very thorough process to become a Family Spirit affiliate.

In terms of what's next for Family Spirit, we want to look into ways that we can continue to partner with Indian Health Service. So currently, we have a contract between Indian Health Service Community Health Representatives, so CHR Program, to train six IHS CHR programs to implement Family Spirit. So the CHR is just a very natural fit for the health educator role. They're para-professionals, they are trained, they know the community well and it's worked out really well. In the pilot year, we trained Comanche, Blackfeet and Pine Ridge; so Comanche, Oklahoma, Blackfeet, Montana, Pine Ridge, South Dakota, and then this year we're training the California Area up in Chico or Willows, California. We're expanding in the Oklahoma Area, and then we are also going to train the Cheyenne River Sioux Tribe CHR program.

So, it's working out really well. We're really happy with the way it's gone and we look forward to continuing this partnership. We've recently been contacted by Navajo Nation Special Diabetes Program because they've recognized and really embraced how as Allison mentioned Family Spirit does address obesity related risk factors. So, we're really looking into how we can expand this partnership as well.

Dr. Bullock, did you want to go ahead and close out the presentation for us.

Dr. Ann Bullock:

Great. Wonderful! Allison, Jenny, thank you so much for that fabulous description of Family Spirit.